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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,903	11/20/2001	Emad S. Alnemri	480140.434D1	1791

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EXAMINER

NICKOL, GARY B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 01/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/989,903

Applicant(s)

ALNEMRI ET AL.

Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 02 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

The petition filed under 37 CFR 1.137(b) to withdrawn abandonment has been granted. Hence, the amendment filed October 2, 2003 (Paper No. 16) in response to the non-final rejection mailed March 3, 2003 (Paper No. 12) has been entered.

Claims 56-64 are pending and are currently under consideration.

Rejections Maintained:

Claims 56-64 remain rejected under 35 U.S.C. 112, first paragraph scope of enablement because the specification, while being enabling for an isolated antibody or an antigen binding fragment thereof specific for a caspase-14 polypeptide comprising SEQ ID NO. 2 or SEQ ID NO:5 does not reasonably provide enablement for the newly amended claims inclusive of all antibodies that would be expected to be specific for any and all fragments of SEQ ID NO:2 or SEQ ID NO:5 for the reasons of record in Paper No. 12, pages 2-5.

Applicants submit (Paper No. 16, page 5) that the rejection has been overcome with the deletion of the 80% identity language. This argument has been considered but is not found persuasive because applicant's amendment of the claims to include a fragment thereof broadens the scope of the invention to include any and all fragments including those fragments that have greater than 80% identity to SEQ ID NO:2 or 5. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

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Claims 61-64 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Rasmussen *et al.* (Electrophoresis, Vol. 13, pages 960-969, 1992) for the reasons of record in Paper No. 12, pages 7-8.

Applicants only note (Paper No. 16, page 5) that they have amended the claims to focus on one aspect of the invention and request that the rejection be withdrawn. This argument has been considered but is not found persuasive because applicants have not clearly set forth on the record how the prior art does not render the claimed invention obvious. Rasmussen *et al.* clearly teach an isolated polypeptide that is nearly identical to SEQ ID NO:5 wherein the manufacture of such antibodies is obvious to those of ordinary skill in the art. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

New Rejections:

Claims 56-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasmussen *et al.* (Electrophoresis, Vol. 13, pages 960-969, 1992).

Claims 61-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasmussen *et al.* (Electrophoresis, Vol. 13, pages 960-969, 1992) for the reasons set forth above and for the reasons of record.

Claims 56-60 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Rasmussen *et al.* as set forth below:

The newly amended claims are drawn to an isolated antibody or an antigen binding fragment thereof specific for a caspase-14 polypeptide, wherein said polypeptide comprises SEQ ID NO:2 or a fragment thereof. Rasmussen *et al.* teach an isolated polypeptide that is nearly 70%

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identical to SEQ ID NO:2 (see attached sequence listing) which encompasses a fragment thereof of SEQ ID NO:2. Accordingly, It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to produce an isolated antibody such as monoclonal antibodies to the antigen identified by Rasmussen *et al.* because the Board of Patent Appeals and interferences has taken the position that once an antigen has been isolated, the manufacture of monoclonal antibodies against it is *prima facie* obvious. See Ex parte Ehrlich, 3 USPQ 2d 1011 (PTO Bd. Pat. APP. & Int. 1987), Ex parte Sugimoto, 14 USPQ 2d 1312 (PTO Bd. Pat. APp. & Int. 1990). Further, one would have a reasonable expectation that such antibodies would bind to a fragment thereof (of SEQ ID NO:2) because of the high degree of amino acid similarity between the prior art polypeptide and SEQ ID NO:2. Thus, to make such antibodies, it would have been further obvious to include an isolated cell expressing the monoclonal antibody because the manufacture of such antibodies by the use of tumor-fused spleen cells to produce hybridomas was well known to those of ordinary skill at the time the article was published. It would have been further *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to produce polyclonal antibodies by immunization techniques for the purposes of isolating and studying the expressed protein as well as producing antigen binding fragments that comprise an Fv portion because the use of such polyclonal antibodies and truncated portions thereof are well-known and conventional in the art.

All other rejections and or objections are withdrawn in view of applicant's amendments and or arguments there to.

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No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
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GBN
January 5, 2004

A handwritten signature in cursive script, reading "Gary B. Nickol".